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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,307	10/09/2003	Patrick J. Sweeney	029815-0104	7309
23524	7590	12/13/2007		
FOLEY & LARDNER LLP 150 EAST GILMAN STREET P.O. BOX 1497 MADISON, WI 53701-1497			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 12/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/682,307

Applicant(s)

SWEENEY, PATRICK J.

Examiner

Laura A. Bouchelle

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/07 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 22, 24, 26-29, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Cole et al (US 6387098). Cole discloses a method of administering fluid to bone comprising introducing a bone nail to a bone, the nail comprising a shaft that is cannulated and comprises fenestrations, and an insert 14 that is cannulated and comprises fenestrations. The device is used to mend a peripheral skeletal fracture, an infusion pump is attached to the insert (see abstract).

4.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 23, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al (US 6387098) in view of Grayson (US 6210376).

7. Claim 23 differs from Cole in calling for the insert to be introduced into the screw before the screw is introduced into the bone. Grayson teaches a method for inserting a cannulated delivery pin into a bone including the steps on inserting an insert 11 into a bone screw 12 prior to inserting the screw into the bone so that the insert prevents the in growth of bone into the cannulated screws (Col. 2, lines 48-53; Col.8, lines 1-7). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cole to include the step of inserting the insert into the screw prior to inserting the screw into the bone as taught by Grayson so that the insert prevents bone in growth into the screw.

8. Claim 25 differs from Cole in calling for a bone screw. Cole teaches a bone nail. Grayson teaches a method of delivering a substance to a bone using a screw having threads 50 that allow for the screw to be secured in the bone. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cole to use a screw as taught by Grayson because a screw is a well know substitute for a nail and a screw fixes the device securely into the bone.

9. Claims 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Wigness et al (US 5203770). Claims 30, 31 differ from Cole in calling for the reservoir or the pump to be implanted subcutaneously. Wigness teaches a method for bone catheterization comprising the steps of inserting a screw into the bone and attaching the end of the screw to a reservoir and a pump that are implanted subcutaneously so that the device can be used for long term delivery of a substance to the patient (Col. 9, lines 33-42). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cole to include an implanted pump and reservoir as taught by Wigness so that the device can be used for long-term delivery of a substance to the patient.

10. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cole in view of Gustilo (US 6019761). Claim 32 differs from Cole in calling for the insert to comprise a balloon to form a seal between the insert and the bone screw. Gustilo teaches an intramedullary nail and method comprising an insert 96 having a balloon 98 to seal the insert and the bone screw 22 so that substances cannot escape through the screw (Col. 10, lines 53-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Cole to include the step of inflating a balloon on the insert to seal the screw as taught by Gustilo so that substances cannot escape through the screw.

Response to Arguments

11. Applicant's arguments with respect to claims 22, 24-29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Laura A Bouchelle
Examiner
Art Unit 3763

